CHICKEN SOUP FOR THE BUSY COORDINATOR

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Best Practices to Ensure Timely Submission to IRB for Study Continuing Review

Scenario:
Professor X is the PI of protocol Lemon that was approved by NHG DSRB. Just prior to the study's IRB approval expiry, the PI submitted the Study Status Report (SSR) late (less than 1 month) to the DSRB for continuing review. The study's ethics approval was not able to be renewed on time and lapsed. As a consequence, all research activities (e.g. recruitment, intervention & data collection), had to be halted until DSRB's continuing review approval was obtained.
To prevent such cases from happening in the future, what should Professor X / PIs of studies do?

The Institution's Research Office advised the PI the following best practices and tips when **Submitting Study Status Report (SSR) to the IRB for continuing review:**

Who?	The **PI** is responsible for the submission of the **SSR** for **continuing review** by the approving IRB well before the expiration date, allowing ample time for IRB's review and approval.
What?	The **SSR Form** includes the following information on the progress of the study (but not limited): ▪ Patient enrollment numbers and breakdown by gender ▪ Description of language and type of participant enrolled ▪ Informed Consent procedure and documentation ▪ Informed Consent Form used ▪ Any UPIRTSO events ▪ DSRM and interim reports
When & Where?	It is best to start SSR **drafting 3 to 3.5 months** before study expiry to ensure ample time for collection of information and submit via ECOS a completed SSR **at least 4-6 weeks** before the study approval period ends (as indicated in the approval letter of the study) for review by the IRB secretariat.
How?	▪ Send a **calendar invite** to key personnel(s) for when to start drafting SSR and ensure the **PI is available** to submit the form. ▪ Reach out to **other sites** (if applicable) to **input** the **information** in the SSR. ▪ After submission of SSR to do **continuous checks** to ensure that all **queries raised** are **answered timely** to ensure successful submission. ▪ If the above conditions were met and the **approval** is **not granted** close to the expiry date, do **contact** the **IRB to check**.

Reference: NHG Investigator Manual Chapter 3.3.4 – Communications with DSRB, 4.6 – Continuing Review, 4.6.1 – Supporting documents for continuing review, 4.6.4 – Criteria for Continuing Review
Additional reading: NHG Investigator Manual Chapter 4.9 – Changes in Study Status, NHG Proper Conduct of Research SOP 501-B0

Article Contributed By: **Edmund Yew Kin Choong, Clinical Research Coordinator & Melissa Low, Senior Clinical Research Coordinator, TTSH CRIO-CTU**
Edited By: NHG Group Research & Innovation, OHRPP

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(researchcoord@nhg.com.sg)